510(k) SUMMARY

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SUBMITTER NAME: Ascension Orthopedics, Inc.
8700 Cameron Road, C–100
Austin, TX 78754-3832

510(k) CONTACT: Glen Neally
Phone: (512) 836-5001

JUN 22 2007

TRADE NAME: Ascension® HRA® System TPS/HA

COMMON NAME: Sterile Resurfacing Shoulder Joint Replacement Prosthesis

CLASSIFICATION: 21 CFR 888.3690

PRODUCT CODE: HSD

PANEL: Orthopedic

PREDICATE DEVICES:
Biomet Copeland Humeral Resurfacing Head (K010664, K010827 and K051843)
DePuy Global C.A.P. (K031971 and K033516)
Ascension® Humeral Resurfacing Arthroplasty (HRA) System (K062861)

DEVICE DESCRIPTION:
The Ascension® HRA® System TPS/HA includes an anatomically designed, semi-constrained, monolithic device designed for resurfacing of the humeral head (hemi-shoulder). The system is designed for non-cemented (i.e. press-fit) fixation. Each device is boxed individually and delivered sterile for single use. The system incorporates eight anatomically designed head geometries with appropriately sized stems. Head sizes are identified using width and height (in millimeters). The Ascension® HRA® device incorporates design features for replacing the damaged humeral head bearing surface and restoring normal anatomy with minimal bone resection. The stem is tapered and fluted to provide rotational as well as axial stability of the seated implant. System instrumentation, including a range of implant trials, is designed to offer precise implant preparation. The HRA device is made from Cobalt Chrome (ASTM F-1537 wrought or ASTM F-75 cast) and features a highly polished bearing surface with a CP Titanium or HA plasma spray under-surface and stem coating for osseointegration. No new materials are introduced with this device. Ascension® HRA® System components will be manufactured by contract manufacturers per Ascension Orthopedics, Inc., specifications.

INTENDED USE:
The Ascension® HRA® System TPS/HA is intended for resurfacing of the humeral head due to:

- Patients disabled by either non-inflammatory or inflammatory arthritis (i.e. rheumatoid arthritis, osteoarthritis and avascular necrosis)
- Mild or moderate humeral head deformity and / or limited motion

- Post-traumatic arthritis

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- Patients with an intact or reparable rotator cuff

BASIS OF SUBSTANTIAL EQUIVALENCE:
A comparison of identical materials and nearly identical design features, demonstrates that the Ascension® HRA® device is substantially equivalent to the predicate device as indicated in the chart below:

Specification / Characteristic	**Ascension Orthopedics Inc (AOI) Humeral Resurfacing Arthroplasty (HRA) Device (& TPS/HA)**	**Biomet / Copeland Humeral Resurfacing Head**	**DePuy / Global C.A.P.**
FDA 510(k) clearance	K062861 (this submission)	K010664, K010827, and K051843	K031971 and K033516
Use	Single use	Single use	Single use
Implantation duration	Longer than 30 days	Longer than 30 days	Longer than 30 days
Constraint	Semi-constrained	Semi-constrained	Semi-constrained
Articulating Surface	ASTM F-75 Co-Cr Casting Alloy or ASTM F1537 wrought Co-Cr	ASTM F-75 Co-Cr Casting Alloy	ASTM F-75 Co-Cr Casting Alloy
Under-Coating	CP Ti (ASTM F1580) HA (ASTM F 1185-03) Plasma Spray Coating	CP Ti (ASTM F1580) Plasma Spray Coating	Porocoat® Porous Coating
Sizes	8	8	10
Width Range	40mm – 56mm	42.7mm – 54.0mm	40mm – 56mm
Height Range	15mm – 21mm	12.0mm – 27.0mm	15mm – 21mm
Radius Range	20.5mm – 29.2mm	25mm - 27.5mm	20.1mm – 30.8mm
Shell Thickness (head)	Same	Same	Same
Under-surface Flat	No	No	Yes
Primary Fixation	Press Fit Stem	Press Fit Stem	Press Fit Stem
Tapered Stem	Yes	Yes	Yes
Stem Cross-Section	Four-Fluted	Four-Fluted	Four-Fluted
Variable Stem Lengths	Yes	Yes	Yes
Cannulated Instrumentation	Yes	Yes	Yes
Minimal Bone	Yes	Yes	Yes

Removal			
Penetration of Intramedullary Canal	No	No	No
Easy Conversion to Stemmed Component	Yes	Yes	Yes

Similarities of the Ascension® HRA® device and the Biomet Copeland and the DePuy Global C.A.P. devices include: All devices have the same indications for use; All devices are made of the same industry standard materials; No new materials are introduced; Minimal bone removal surgical procedure for all device; Anatomic head sizes; All devices incorporate a press-fit stem as the primary fixation method; All devices are intended for surgical implantation longer than 30 days: All devices are intended for single use only.

Summary:
The Ascension® HRA® System TPS/HA is identical functionally, and had the same indications for use when compared to the predicate devices, and is fabricated from the same materials as the predicate devices. Dimensionally, the Ascension® HRA® device is nearly identical to the predicate devices. Devices for the subject and predicate systems are provided sterile in individual packages. Therefore, the Ascension® HRA® device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 2 2007

Ascension Orthopedics, Inc.
% Mr. Glen Neally
Vice President of QA/RA/CA
8700 Cameron Road, Suite 100
Austin, Texas 78754-3832

Re: K071064
Trade/Device Name: Ascension® Humeral Resurfacing Arthroplasty (HRA) System TPS/HA
Regulation Number: 21 CFR 888.3690
Regulation Name: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Regulatory Class: II
Product Code: HSD
Dated: April 12, 2007
Received: April 16, 2007

Dear Mr. Neally:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

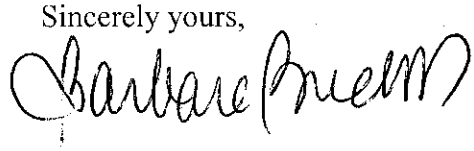
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality

systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(K) Number: K071064 (pg 1/1)

Device Name: Ascension® Humeral Resurfacing Arthroplasty (HRA) System TPS/HA

Indications for Use:

The Ascension® HRA® device is intended for resurfacing of the humeral head due to:

- Patients disabled by either non-inflammatory or inflammatory arthritis (i.e. rheumatoid arthritis, osteoarthritis and avascular necrosis).
- Mild or moderate humeral head deformity and / or limited motion.
- Post-traumatic arthritis.
- Patients with an intact or reparable rotator cuff.

Prescription Use ___X___ (Part 21 CFR 801Subpart B) OR Over-The-Counter Use _____ (Part 21 CFR 801Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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